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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,588	11/29/2001	Chen Xing Su	10209.353	6233

21999 7590 12/21/2005  
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EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1655

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,588

Applicant(s)

SU ET AL.

Examiner

Patricia Leith

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-23, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-12 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/03/05 has been entered.

Claims 1 and 4-28 are pending in the application.

Claims 13-23 were withdrawn from the merits as being directed toward a non-elected invention per the election without traverse in the Office Action dated 6/18/03. Claims 27 and 28 were also withdrawn from consideration as being drawn to a non-elected invention due to election by original presentation in the Office Action dated 2/11/03.

Claims 1, 4-12 and 24-26 were examined on their merits.

*Morinda citrifolia* may be referred to as 'MC' in this Office Action.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) and further in view of Gagnon (1997).

Chye (8/10/1999) reporting for the New Straits Times indicated that Morinda Inc. sold a beverage containing *Morinda citrifolia* juice, grape juice and blueberry juice (see page 3). Chye explained that grape juice and blueberry juice were added to the MC juice in order to "neutralise [sic] its pungent odour and horrible taste". It is clear from the article by Chye that the beverage sold by Morinda Inc. was consumed by people, including patients with diseases such as cancer (see pages 1 and 2).

Chye did not report wherein the *Morinda citrifolia* juice was consumed in order to scavenge lipid hydroperoxides and superoxide anion free radicals, wherein the *Morinda*

*citrifolia* was present in the composition from about 10 to 99.99 percent by weight, wherein the MC juice contained pulp or wherein the composition was taken on an empty stomach.

Schechter (1998) reporting for Better Nutrition indicated that, "...the noni plant has been used for centuries by the native people as an extremely important health remedy" (p. 1, ProQuest direct print-out). Schechter further pointed out that:

"Noni stimulates and enhances your immune system, including macrophages and lymphocytes – vital components of your body's natural defenses. Noni fruit also contains two of the best antioxidants- vitamin C and selenium plus other substances that counteract inflammatory and irritating free radicals in your body, reduce inflammation and significantly decrease pain" (p. 2, ProQuest direct print-out).

Thus, noni was already known in the art as an antioxidant. An antioxidant would intrinsically scavenge lipid hydroperoxides and superoxide anion free radicals in the body.

Gagnon (1997) suggested '...taking extracts between meals, apart from food, because that is when they are more easily absorbed by the body. This way ,extracts enter the bloodstream readily and immediately start the healing process' (p.27).

The ordinary artisan would have been motivated to ingest the noni juice on an empty stomach in order to have allowed the juice to be absorbed by the body more readily, thereby obtaining the maximum medicinal benefit of the juice.

The prior art did not state wherein the MC was present in the composition from about 10 to 99.99 percent of the composition; however, it is clear from Chye that MC was the therapeutically active ingredient of the composition. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

It is further deemed that because MC juice intrinsically scavenges lipid hydroperoxides and superoxide anion free radicals (i.e., it possesses antioxidant properties) that ingestion of the MC juice of the prior art would have also provided for this effect. One of ordinary skill in the art would have been motivated to ingest a juice containing MC, blueberry and grape juice in order to scavenge lipid hydroperoxides and superoxide anion free radicals to increase better health, especially considering MC was already known to be an antioxidant.

It is well known in the art that juice is sold with and without pulp. It is not *a priori* known if the *Morinda citrifolia* juice reported by Chye contained, or did not contain, pulp. However, it is deemed that the addition or removal of pulp from the juice would have merely been a matter of design choice. Pulp is merely fibrous matter which encapsulates the juice, providing little if no nutritional/therapeutic value. One of ordinary skill in the art would have been motivated to leave the pulp in the juice, in order to attract consumers who prefer pulp in their juice. There is also no indication in the Instant specification that *Morinda citrifolia* juice with pulp or *Morinda citrifolia* juice without pulp makes any measurable difference with regard to inhibiting lipid peroxidation.

Applicants' arguments pertaining to the previous rejections are essentially moot in light of the new rejection *supra*; however, arguments which may pertain to this new rejection were fully considered, but not found persuasive.

Applicant argues that none of the references teaches consuming *Morinda citrifolia* juice to inhibit, prevent or treat lipid peroxidation. Further, Applicant points out and attaches a portion of provisional application 06/251,417 and states that "the levels of lipidperoxidation inhibition experienced by utilizing the products and methods of the present invention are not merely intrinsic [*sic*] properties of *Morinda citrifolia*" (p. 10, Arguments). However, it is clear from Schechter that noni intrinsically contains antioxidants which would therefore scavenge lipid hydroperoxides as well as superoxide

anion free radicals. Further, according to the data provided by 60/251,417 all concentrations of Tahitian Noni Juice (TNJ) (aka *Morinda citrifolia* juice) have these properties. It cannot be found where any unexpected result has been achieved.

Applicant further states that '...the addition of pulp and other ingredient do impart increased efficacy as demonstrated by the above mentioned research" (p. 11, Arguments). However, the Examiner cannot determine what part of the attached portion of 60/251,417 provides for these results.

Claims 1, 4-12 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) in view of Gagnon (1997) in view of Brock et al. (1991) and further in view of Nahir (EP 0 555 573 A1).

The teachings of Chye, Schechter and Gagnon were discussed supra. None of the reference specifically taught the particulars of processing the *Morinda citrifolia* to obtain MC juice or the addition of auxiliary ingredients such as flavorings or sweeteners extracts or colorings.

Milk and juices are routinely pasteurized in order to reduce the amount of bacterial contaminants as well as preserve the beverages for longer amounts of time according to Brock et al. (1991). Specifically, Brock et al. taught that pasteurization was found applicable to 'wine, beer, cider, vinegar, milk, and countless other perishable beverages, foods and organic products' (p.334).

Mechanical separation of seeds, peel and pulp from fruit juice was well known, conventional practice in the art at the time the Invention was made: Nahir (EP 0 555 573 A1) disclosed an apparatus for making juice which removed the pulp, peel and seeds from fruit to obtain pulp-free fruit juice (Fig. 1 and p.4, lines 20-56):

"The described movement of the pusher 24 along the axis 40 causes each back flap 31 to engage and thus push a fruit from a corresponding transport location 18 of the feed conveyor to a corresponding pulp removal location. At the same time, front flap 30 is operative to engage an empty fruit peel, from which the pulp has been removed and which is located on one of the doors 20, and to push the fruit peel into a waste conveyor 47" (p.4, lines 24-28).

Further:

"Therefore, as the juice sacs falling into the trough are carried towards the lower end thereof, any fruit seeds that may be present in the flow float to the top and are discharged to a seed reception member 52" (p.4, lines 41-42)

One of ordinary skill in the art would have been motivated to pasteurize the noni juice as disclosed by Mumford (1998) in order to have prolonged the shelf life of the juice. Brock et al. made it clear that pasteurization of beverages was common, routine practice in the art of beverage making, and well within the purview of the ordinary artisan. Although Brock did not specifically teach wherein the liquids were pasteurized at a minimum of 180 ° F, it is deemed that the ordinary artisan would have had a

reasonable expectation that pasteurization at this temperature would have provided enough heat to kill microorganisms present in the juice. As related in the previous Office action, One of ordinary skill in the art would have been motivated to pasteurize the noni juice in order to have prolonged the shelf life of the juice. Brock et al. made it clear that pasteurization of beverages was common, routine practice in the art of beverage making, and well within the purview of the ordinary artisan.

The ordinary artisan would have been motivated to ingest the noni juice on an empty stomach in order to have allowed the juice to be absorbed by the body more readily, thereby obtaining the maximum medicinal benefit of the juice.

One of ordinary skill in the art would have been motivated to have added carriers and sweeteners (whereby a carrier and a sweetener are respectively deemed 'at least one other ingredient') to noni juice in order to have formulated noni juice compositions containing varying percentages of active ingredients (i.e., 'regular' -vs- 'extra strength') as well as for mere ease of delivery. It was routine in the art of pharmacology to admix active ingredients with carriers, colorings and sweeteners for example. Carriers were an advantageous means of diluting active ingredients to necessary dosage ranges. Sweeteners and colorings would have imparted a palatable taste and vibrant color to the composition thereby increasing the marketability of the product. The addition of sweeteners and colorings would not have changed the medicinal qualities of the noni. It is further noted that blueberry juice is a botanical

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extract since blueberry is a botanical and squeezing the juice therefrom results in an extract. It is deemed that blueberry juice as well as grape juice are both nutritional ingredients (claim 7 for example).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

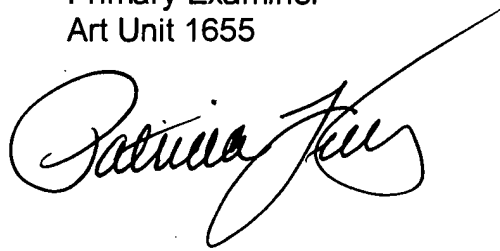
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith  
Primary Examiner  
Art Unit 1655

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a long, sweeping flourish extending from the end of the name.

12/05/05